JAN 2 7 2012 **EXHIBIT#1a**

# 510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K113141

## 1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
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Date Summary Prepared: October 21, 2011

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## 2. Name of the Device:

Microlife Dual Mode Thermometer, Model IFR1MJ1

## 3. Predicate Device Information:

Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1, K#091040

Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, K#033820

## 4. Device Description:

The Microlife Dual Mode Thermometer, Model IFR1MJ1 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperatures from the forehead or auditory canal.

This Dual Mode Thermometer enables very safe and reliable measurements and with its technology the thermometer offers a very high clinical accuracy and has been designed to provide a maximum of user-friendliness.

The Microlife Dual Mode Thermometer consists mainly of six parts:

a) Thermopile Sensor
b) ASIC
c) E2PROM IC
d) LCD and Backlight
e) 2 Buttons, 1 Buzzer, Automatic switch
f) Probe cap

**5. Intended Use:**

The Microlife Dual Mode Thermometer IFR1MJ1 is intended for the intermittent measurement and monitoring of human body temperatures. The device is indicated for use by people above 12 years old to geriatric for ear mode and from newborn to geriatric for forehead mode in the home.

**6. Comparison to Predicate Devices:**

The Microlife Dual Mode Thermometer, Model IFR1MJ1 is substantially equivalent to Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1, K#091040, and Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, K#033820, which has the same intended use and is similar in design to the predicate devices.

The Microlife Dual Mode Thermometer IFR1MJ1 and the predicate devices are identical in the temperature measurements algorithm and fundamental scientific technology, Microlife IFR1MJ1 and IR1DV1-1 mainly differ by appearance, probe cap etc., Microlife IFR1MJ1 and FR1DM1 mainly differ by appearance, backlight, probe cap etc.

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965, as well as IEC60601-1and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

**8. Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted in accordance with ASTM E1965, the bland-Altman plot was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per clinical validation for Microlife Dual Mode Thermometer.

## 9. Conclusions:

The Microlife Dual Mode Thermometer, Model IFR1MJ1 has the same intended use and technological characteristics as the Microlife Digital Infrared Ear Thermometer Model IR1DV1-1 and Microlife Digital Infrared Forehead Thermometer Model FR1DM1. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Dual Mode Thermometer IFR1MJ1 is substantially equivalent to the predicate devices IR1DV1-1 and FR1DM1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 10021

JAN 2 7 2012

Re: K113141
Trade/Device Name: Microlife Dual Mode Thermometer, Model IFR1MJ1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 29, 2011
Received: December 30, 2011

Dear Ms. Goldstein-Flak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**EXHIBIT B**

# Indications for Use

**510(k) Number (if known):** K113141

**Device Name:** Microlife Dual Mode Thermometer, Model IFR1MJ1

**Indications For Use:**

The Microlife Dual Mode Thermometer IFR1MJ1 is intended for the intermittent measurement and monitoring of human body temperatures. The device is indicated for use by people above 12 years old to geriatric for ear mode and from newborn to geriatric for forehead mode in the home.

**Prescription Use** _____ **AND/OR Over-The-Counter Use** __X___
(Part21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

1/25/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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